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Actavis Elizabeth LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS LTD. and ACTELION CLINICAL RESEARCH, INC. Plaintiffs, v. APOTEX INC., APOTEX CORP. and ROXANE LABORATORIES, INC. Defendants, and ACTAVIS ELIZABETH LLC, Intervenor-Defendant/Counterplaintiff	Case No: 1:12-cv-05743 (NLH) (AMD) CIVIL ACTION **ANSWER AND COUNTERCLAIMS OF INTERVENOR-DEFENDANT/ COUNTERPLAINTIFF ACTAVIS ELIZABETH LLC** **JURY TRIAL DEMANDED**

STATEMENT PURSUANT TO L. CIV. R. 10.1

Intervenor-Defendant/Counterplaintiff Actavis Elizabeth LLC is a company organized under the laws of Delaware with a principal place of business at 200 Elmora Avenue, Elizabeth, NJ, 07202. Plaintiff Actelion Pharmaceuticals Ltd. has its principal place of business at

Gewerbestrasse 16, CH-4123 Allschwil, Switzerland. Plaintiff Actelion Clinical Research, Inc. has its principal place of business at 1820 Chapel Avenue West, Suite 300, Cherry Hill, NJ, 08002. Apotex Inc. has its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada, M9L 1T9. Apotex Corp. has its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326. Roxane Laboratories, Inc. has its principal place of business at 1809 Wilson Road, Columbus, Ohio, 43228.

ANSWER

Intervenor-Defendant/Counterplaintiff Actavis Elizabeth LLC ("Actavis"), by and through undersigned counsel, answers Plaintiffs Actelion Pharmaceuticals Ltd. ("APL") and Actelion Clinical Research, Inc.'s ("ACR," and together with "APL," "Actelion") Complaint for Declaratory Judgment ("Complaint") as follows:

NATURE OF THE ACTION

1. The allegations in Paragraph 1 constitute Plaintiffs' characterization of their case and state legal conclusions, and thus do not require a response. To the extent a response is required, Actavis denies the allegations in Paragraph 1.

2. Upon information and belief, admitted that APL obtained approval from the Food and Drug Administration ("FDA") of a new drug application ("NDA") for Tracleer. Upon information and belief, admitted that Tracleer may cause side effects. Upon information and belief, admitted that FDA's approval of Tracleer was subject to Actelion's implementation of a Risk Evaluation and Mitigation Strategy ("REMS"). Actavis denies the remaining allegations of Paragraph 2.

3. Actavis lacks sufficient information to admit or deny the allegations in Paragraph 3, and on that basis, denies them.

4. The allegations in Paragraph 4 constitute Plaintiffs' characterization of their case and state legal conclusions, and thus do not require a response. To the extent a response is required, Actavis denies the allegations in Paragraph 4.

PARTIES

5. Actavis lacks sufficient information to admit or deny the allegations in Paragraph 5, and on that basis, denies them.

6. Actavis lacks sufficient information to admit or deny the allegations in Paragraph 6, and on that basis, denies them.

7. Actavis lacks sufficient information to admit or deny the allegations in Paragraph 7, and on that basis, denies them.

8. Actavis lacks sufficient information to admit or deny the allegations in Paragraph 8, and on that basis, denies them.

9. Actavis lacks sufficient information to admit or deny the allegations in Paragraph 9, and on that basis, denies them.

JURISDICTION AND VENUE

10. The allegations in Paragraph 10 constitute Plaintiffs' characterization of their case and state legal conclusions, and thus do not require a response. To the extent a response is required, Actavis admits that this court has subject matter jurisdiction and denies any remaining allegations in Paragraph 10.

11. The allegations in Paragraph 11 state legal conclusions, and thus do not require a response. To the extent a response is required, Actavis lacks sufficient information to admit or deny the allegations in Paragraph 11, and on that basis, denies them.

12. The allegations in Paragraph 12 state legal conclusions, and thus do not require a response. To the extent a response is required, Actavis lacks sufficient information to admit or deny the allegations in Paragraph 12, and on that basis, denies them.

13. The allegations in the first and second sentences of Paragraph 13 state legal conclusions, and thus do not require a response. To the extent a response is required, Actavis lacks sufficient information to admit or deny all of the allegations in Paragraph 13, and on that basis, denies them.

14. The allegations in the first sentence of Paragraph 14 state legal conclusions, and thus, do not require a response. To the extent a response is required, Actavis lacks sufficient information to admit or deny all of the allegations in Paragraph 14, and on that basis, denies them.

FACTUAL BACKGROUND

15. Admitted that pulmonary arterial hypertension ("PAH") is a disorder. Upon information and belief, admitted that APL submitted an NDA to FDA for PAH treatment. Upon information and belief, admitted that the proprietary name for Plaintiffs' PAH treatment is Tracleer. Actaivs lacks sufficient information to admit or deny the remaining allegations in Paragraph 15, and on that basis, denies them.

16. Actavis denies the allegations in the first sentence of Paragraph 16. Actavis lacks sufficient information to admit or deny the remaining allegations in Paragraph 16, and on that basis, denies them.

17. Upon information and belief, admitted that Tracleer may cause side effects. Upon information and belief, admitted that FDA's approval of Tracleer was conditioned on a REMS. Actavis lacks sufficient information to admit or deny the remaining allegations in Paragraph 17, and on that basis, denies them.

18. Actavis lacks sufficient information to admit or deny the allegations in the final sentence of Paragraph 18, and on that basis, denies them. Actavis denies the remaining allegations in Paragraph 18.

19. Actavis lacks sufficient information to admit or deny the allegations in the final sentence of Paragraph 19, and on that basis, denies them. Actavis denies the remaining allegations in Paragraph 19.

20. Upon information and belief, admitted that Tracleer may cause side effects. Actavis denies the remaining allegations in Paragraph 20.

21. Admitted that generic drug applicants submitting Abbreviated New Drug Applications ("ANDAs") generally must demonstrate bioequivalency to the innovator drug product. Actavis lacks sufficient information to admit or deny the remaining allegations in Paragraph 21, and on that basis, denies them.

22. Actavis lacks sufficient information to admit or deny the allegations in Paragraph 22, and on that basis, denies them.

23. Actavis lacks sufficient information to admit or deny the allegations in Paragraph 23, and on that basis, denies them.

24. To the extent that the allegations in Paragraph 24 suggest that Actelion has no duty or obligation to provide Tracleer to Actavis, or that Actelion is otherwise entitled to any

relief whatsoever, Actavis denies these allegations. Actavis lacks sufficient information to admit or deny the remaining allegations in Paragraph 24, and on that basis, denies them.

25. Actavis lacks sufficient information to admit or deny the allegations in Paragraph 25, and on that basis, denies them.

26. To the extent that the allegations in Paragraph 26 suggest that Actelion has no duty or obligation to provide Tracleer to Actavis, or that Actelion is otherwise entitled to any relief whatsoever, Actavis denies these allegations. Actavis lacks sufficient information to admit or deny the remaining allegations in Paragraph 26, and on that basis, denies them.

27. Actavis lacks sufficient information to admit or deny the allegations in Paragraph 27, and on that basis, denies them.

28. Actavis lacks sufficient information to admit or deny the allegations in Paragraph 28, and on that basis, denies them.

29. Actavis lacks sufficient information to admit or deny the allegations in Paragraph 29, and on that basis, denies them.

30. To the extent that the allegations in Paragraph 30 suggest that Actelion has no duty or obligation to provide Tracleer to Actavis, or that Actelion is otherwise entitled to any relief whatsoever, Actavis denies these allegations. Actavis lacks sufficient information to admit or deny the remaining allegations in Paragraph 30, and on that basis, denies them.

31. Actavis lacks sufficient information to admit or deny the allegations in Paragraph 31, and on that basis, denies them.

32. To the extent that the allegations in Paragraph 32 suggest that Actelion has no duty or obligation to provide Tracleer to Actavis, or that Actelion is otherwise entitled to any

relief whatsoever, Actavis denies these allegations. Actavis lacks sufficient information to admit or deny the remaining allegations in Paragraph 32, and on that basis, denies them.

33. The allegations in the first and second sentences of Paragraph 33 state legal conclusions, and thus, do not require a response. To the extent a response is required, Actavis denies the allegations in the first and second sentences of Paragraph 33. The remaining allegations in Paragraph 33 purport to summarize provisions of the Food and Drug Amendments Act of 2007, 21 U.S.C. § 355-1 (the "REMS statute"), and the Tracleer REMS, along with Actelion's duties thereunder. Insofar as these allegations consist of conclusions of law, no response is required. To the extent that the allegations may be deemed to state allegations of fact, the cited statute and REMS speak for themselves and are in their entirety the best evidence of their content. Actavis denies any allegations that are inconsistent with the plain language of the statute and Tracleer REMS.

34. The allegations in Paragraph 34 state legal conclusions, and thus, do not require a response. To the extent a response is required, Actavis denies the allegations in Paragraph 34.

35. The allegations in Paragraph 35 state legal conclusions, and thus, do not require a response. To the extent a response is required, Actavis denies the allegations in Paragraph 35.

36. The allegations in Paragraph 36 purport to summarize provisions of the REMS statute. Insofar as these allegations state conclusions of law, no response is required. To the extent that the allegations may be deemed to state allegations of fact, the cited statute speaks for itself and is in its entirety the best evidence of its content. Actavis denies any allegations that are inconsistent with the plain language of the statute.

37. The allegations in Paragraph 37 purport to summarize and quote from provisions of the REMS statute and its legislative history. Insofar as these allegations state conclusions of

law, no response is required. To the extent that the allegations may be deemed to state allegations of fact, the cited statute and its legislative history speak for themselves and are in their entirety the best evidence of their content. Actavis denies any allegations that are inconsistent with the plain language of the statute and its legislative history.

38. The allegations in Paragraph 38 purport to summarize and quote from provisions of the Food and Drug Administration Safety and Innovation Act and its legislative history. Insofar as these allegations state conclusions of law, no response is required. To the extent that the allegations may be deemed to state allegations of fact, the cited statute and its legislative history speak for themselves and are in their entirety the best evidence of their content. Actavis denies any allegations that are inconsistent with the plain language of the statute and its legislative history.

39. The allegations in Paragraph 39 state legal conclusions, and thus, do not require a response. To the extent a response is required, Actavis denies the allegations in Paragraph 39.

40. The allegations in Paragraph 40 state legal conclusions, and thus, do not require a response. To the extent a response is required, Actavis denies the allegations in Paragraph 40.

41. The allegations in the final sentence of Paragraph 41 state legal conclusions, and thus, do not require a response. To the extent a response is required, Actavis denies the allegations in the final sentence of Paragraph 41. Actavis lacks sufficient information to admit or deny the remaining allegations in Paragraph 41, and on that basis, denies them.

42. The allegations in Paragraph 42 state legal conclusions, and thus, do not require a response. To the extent a response is required, Actavis denies the allegations in Paragraph 42.

43. The allegations in Paragraph 43 state legal conclusions, and thus, do not require a response. To the extent a response is required, Actavis denies the allegations in Paragraph 43.

44. The allegations in the first sentence of Paragraph 44 state legal conclusions, and thus, do not require a response. To the extent a response is required, Actavis denies the allegations in the first sentence of Paragraph 44. Actavis denies the remaining allegations in Paragraph 44.

45. The allegations in Paragraph 45 state legal conclusions, and thus, do not require a response. To the extent a response is required, Actavis denies the allegations in Paragraph 45.

COUNT I
(Declaratory Relief)

46. Actavis incorporates the answers to Paragraphs 1 through 45 as though more fully set forth herein.

47. Actavis lacks sufficient information to admit or deny the allegations in the first and second sentences of Paragraph 47, and on that basis, denies them. To the extent that the allegations in Paragraph 47 suggest that Actelion has no duty or obligation to provide Tracleer to Actavis, or that Actelion is otherwise entitled to any relief whatsoever, Actavis denies these allegations. The allegations in the final sentence of Paragraph 47 state legal conclusions, and thus, do not require a response. To the extent that a response is required, Actavis denies the allegations in the final sentence of Paragraph 47.

48. Actavis lacks sufficient information to admit or deny the allegations in Paragraph 48, and on that basis, denies them. To the extent that the allegations in the second sentence of Paragraph 48 suggest that Actelion has no duty or obligation to provide Tracleer to Actavis, or that Actelion is otherwise entitled to any relief whatsoever, Actavis denies these allegations.

49. Actavis lacks sufficient information to admit or deny the allegations in Paragraph 49, and on that basis, denies them.

50. Actavis admits there is an actual controversy regarding Actelion's refusal to sell samples of Tracleer to generic manufacturers. The remaining allegations in Paragraph 50 state legal conclusions, and thus, do not require a response. To the extent that a response is required, Actavis denies the allegations in Paragraph 50.

51. Actavis denies the allegations in Paragraph 51.

PRAYER FOR RELIEF

The remainder of the Complaint consists of Plaintiffs' Prayer for Relief, which requires no response. To the extent that a response is required, Actavis denies that Plaintiffs are entitled to the relief sought in the Complaint or to any relief whatsoever.

WHEREFORE, Actavis respectfully requests that the Court enter judgment (1) denying any relief sought by Actelion in its Complaint; and (2) for any additional relief in Actavis's favor that the Court deems just and proper.

GENERAL DENIAL

Except as expressly admitted, Actavis denies each and every allegation contained in Plaintiffs' Complaint and denies that the Plaintiffs are entitled to any relief sought in the Complaint or to any relief whatsoever.

AFFIRMATIVE DEFENSES

Actavis hereby asserts the following affirmative defenses without assuming the burden of proof for issues where the burden would not ordinarily be upon the responding party.

First Affirmative Defense

(Failure to State a Cause of Action)

The cause of action asserted in the Complaint fails to state a claim for which relief can be granted.

Second Affirmative Defense

(Equitable Estoppel)

As a result of their own acts and omissions, Plaintiffs are estopped, in whole or in part, from maintaining the cause of action asserted in, or obtaining the relief sought by, the Complaint.

Third Affirmative Defense

(Laches)

The Complaint, and the cause of action allegedly contained therein, is barred, in whole or in part, by the doctrine of laches, in that Plaintiffs have unreasonably delayed asserting their alleged claim, and such delay has caused great prejudice to Actavis.

Fourth Affirmative Defense

(Justiciability)

The Complaint, and the cause of action allegedly contained therein, is barred, in whole or in part, because it does not present a justiciable controversy.

Fifth Affirmative Defense

(Additional Affirmative Defenses)

Actavis presently has insufficient knowledge or information upon which to form a belief as to whether it may have additional, as yet unstated, affirmative defenses. Actavis reserves the right to assert additional affirmative defenses in the event such defenses become appropriate.

COUNTERCLAIMS

Intervenor-Defendant/Counterplaintiff Actavis, by and through counsel, hereby counterclaims against Plaintiffs and Counter-Defendants Actelion as follows:

NATURE OF THE LAWSUIT

1. The fundamental issue in this case is whether Actelion, a branded pharmaceutical manufacturer, can preclude all generic competition for its drug products by shutting down the generic drug regulatory approval pathway created by Congress, where such conduct raises costs for health insurers, health care providers, the federal government, patients and consumers. Actelion's conduct is contrary to antitrust law and is inconsistent with the Hatch-Waxman Act, which Congress enacted to facilitate generic drug competition by creating the specific approval pathway that Actelion now attempts to block.

2. Actavis is an industry leader in the development, manufacture, and sale of high-quality generic pharmaceuticals. Actavis is a generic drug manufacturer seeking to file an Abbreviated New Drug Application ("ANDA") referencing Tracleer (the brand name for bosentan), a "pulmonary arterial hypertension" ("PAH") drug manufactured by Actelion Pharmaceuticals. PAH is a rare, chronic, life-threatening disorder that severely compromises the functions of the lungs and heart. Upon FDA approval of this ANDA, Actavis intends to market a generic version of Tracleer (also described herein as the "generic bosentan product").

3. Actavis is actively developing a proposed generic bosentan product. To date, it has made a considerable investment in, among other things, conducting various required studies, developing a prototype, and manufacturing "pilot bio-batches." To obtain FDA approval, Actavis must show, among other things, that its generic bosentan product is bioequivalent to Actelion's FDA-approved branded Tracleer product. To demonstrate bioequivalence, Actavis must perform extensive and thorough bioequivalence tests. These tests necessitate that the generic drug manufacturer have access to samples of the brand-name drug in order to compare it with the proposed generic version.

4. Under most circumstances, generic manufacturers may obtain samples of brand-name drugs for testing purposes from pharmaceutical wholesalers or other distributors. However, because Tracleer may cause serious side effects, as a condition of Tracleer's approval, the FDA required that Tracleer be subject to certain restrictions as to the manner of distribution and use. As a result of these limitations, Actavis cannot obtain Tracleer samples for bioequivalence testing purposes from sources that are normally available for other brand-name drugs. Actelion has entered into agreements with the wholesalers and distributors of Tracleer that precludes the supply of Tracleer to Actavis and similarly situated generic manufacturers. (Complaint ¶¶ 18-19.) Instead Actavis and other generic manufacturers *can only obtain Tracleer directly from Actelion, the brand manufacturer*.

5. Despite the fact that it is the only source (or perhaps because of it), Actelion has refused Actavis's request to purchase Tracleer samples for its bioequivalence testing. The stated reasons for this refusal are transparently pretextual. Actelion's refusal means that Actavis cannot conduct the testing that the FDA requires so that it can bring its generic bosentan product to market. As a result of Actelion's conduct, Actavis is suffering irreparable harm and injury to its business. In addition, Actelion's conduct is causing consumers harm: by preventing the entry of a lower-priced generic bosentan product, Actelion is forcing all bosentan purchasers and all third-party payors who ultimately bear the cost of bosentan prescriptions to pay supra-competitive prices for Tracleer.

THE PARTIES

6. Defendant-Counterplaintiff Actavis Elizabeth LLC is a pharmaceutical company with its principal place of business at 200 Elmora Avenue, Elizabeth New Jersey, 07202.

Actavis and its affiliates are industry leaders in the development, manufacture, and sale of high-quality generic pharmaceuticals.

7. Defendant Apotex Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada, M9L 1T9. Upon information and belief, Apotex Inc. is in the business of making and selling generic drug products.

8. Defendant Apotex Corp. is a Delaware corporation with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326. Upon information and belief, Apotex Corp. is in the business of making and selling generic drug products.

9. Defendant Roxane is a Nevada corporation with its principal place of business at 1809 Wilson Road, Columbus, Ohio, 43228. Upon information and belief, Roxane is in the business of making and selling generic drugs.

10. Plaintiff/Counter-Defendant Actelion Pharmaceuticals Ltd. ("APL") is a pharmaceutical company with its principal place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland.

11. Plaintiff/Counter-Defendant Actelion Clinical Research, Inc. ("ACR") is a Delaware corporation with its principal place of business at 1820 Chapel Avenue West, Suite 300, Cherry Hill, NJ, 08002. Upon information and belief, ACR is an affiliate of APL and manages the Tracleer NDA and Tracleer REMS in the United States as agent for APL.

JURISDICTION AND VENUE

12. This Court has federal question jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337(a) because Actavis brings its claims under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26 and the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, to secure a

declaratory judgment and to recover treble damages and costs of suit, including reasonable attorneys' fees, against Actelion for the injuries sustained by Actavis by reason of the violations, as hereinafter alleged, of Section 2 of the Sherman Act, 15 U.S.C. § 2. This action is also instituted to secure injunctive relief against Actelion to prevent it from further violating Section 2 of the Sherman Act.

13. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1367.

14. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b) and (c).

15. This Court has personal jurisdiction over Actelion because it has ongoing and continuous contacts with this judicial district, ACR's principal place of business lies within this judicial district, and both ACR and APL have clearly purposefully availed themselves of the benefits of this judicial district by filing their Complaint here.

TRADE AND COMMERCE

16. Actelion is engaged in interstate commerce and in activities substantially affecting interstate commerce, and the conduct alleged herein substantially affects interstate commerce. Actelion has subsidiaries with marketing and sales in more than 20 countries, and covers all key pharmaceutical markets worldwide. Doctors across the county are able to prescribe Tracleer, and Actelion sells Tracleer to patients throughout the United States. By engaging in anticompetitive conduct to prevent generic entry, Actelion forces consumers in all states to pay supra-competitive prices for Tracleer.

FACTS

I. CONGRESS ENACTED THE HATCH-WAXMAN ACT TO PROVIDE AN EXPEDITED PROCESS FOR GENERIC DRUG ENTRY

17. The statutory framework at issue in this case includes the Food and Drug laws, the antitrust laws, and the intellectual property laws.

A. The Hatch-Waxman Act

18. Under the Food and Drug laws, a pharmaceutical company must obtain FDA approval to market a prescription drug through the submission of a New Drug Application ("NDA"). This application must contain safety and efficacy studies and specify the components and composition of the drug, the methods and facilities used in "the manufacture, processing and packaging" of the drug, the proposed drug labeling, and any patents issued on the composition or methods of using the drug. 21 U.S.C. § 355(b)(1).

19. Before 1984, a drug company wishing to supply a generic version of a drug already approved under an NDA was also required to undertake its own costly studies regarding the efficacy and safety of a drug and to file its own NDA for approval. In 1984, however, Congress recognized the futility and waste inherent in requiring every potential generic supplier to conduct its own studies and to submit its own NDA for drugs whose safety and efficacy had already been established. Accordingly, Congress created an expedited regulatory approval pathway for generic drugs in the Drug Price Competition & Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (codified at various sections of Titles 21 and 35 of the United States Code).

20. Among its key provisions, the Hatch-Waxman Act created the ANDA process, making it possible to bring generic drugs to market while avoiding the duplicative safety and

efficacy studies, thereby increasing competition in the pharmaceuticals industry. The Act allowed generic drugs to enter the market without repeating expensive and lengthy clinical trials required for their brand-name counterparts. Instead, the Act only requires proof that the generic is "the same" as an FDA-approved brand-name drug in all essential respects, including proof that the generic is "bioequivalent to" the approved drug referenced in the ANDA, i.e., the reference listed drug ("RLD"). 21 U.S.C. § 355(j)(2)(A).[1]

21. The Hatch-Waxman Act was not one-sided in that it also provided additional protections that were valuable for brand-name drug manufacturers. Specifically, the Act provided brand manufacturers with an opportunity for five years of exclusivity for new chemical entities (regardless of patent protection), *see* 21 U.S.C. § 355(j)(5)(F)(ii), and five additional years of patent protection for their drugs upon request, *see* 35 U.S.C. § 156. This was the central compromise behind the legislation: brand-name manufacturers obtained longer exclusivity and patent protection in exchange for faster and cheaper generic entry once the exclusivity periods and patent protection ultimately expired.

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[1] Bioequivalence is defined as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 CFR § 320.1. After proving bioequivalence, an ANDA filer must explain how its generic product would not infringe any patent held by the brand-name drug referenced in the application. The ANDA applicant can either certify that (1) the brand-name product does not have a patent, (2) the brand-name drug patent has expired, (3) the brand-name drug patent is expiring soon and the generic product will not enter the market until the patent has expired, or (4) the brand-name drug patent is invalid or will not be infringed by the generic product. The last certification allows generic developers to challenge the patents allegedly protecting brand-name drugs, enabling them to more easily prevent invalid patent holders from exploiting the term of exclusivity that is intended by law to be afforded only to valid patent holders.

22. The Hatch-Waxman Act was a critical impetus to the growth of the generic drug industry. Previously, generic drugs made up only 12 percent of all U.S. prescriptions. In 2011, nearly 80 percent of the 4 billion prescriptions written in the U.S. were filled using generic medicines, while accounting for only 27 percent of total drug spending.

23. Generic entry creates competition that not only brings down the prices of brand-name drugs, but results in the sale of less-expensive generic versions of the branded drugs, thereby providing significant savings to consumers and reducing overall health care costs. On average, the retail price of a generic drug is 75 percent lower than the retail price of a brand-name drug. *See* U.S. Gov't Accountability Office, GAO-12-371R, Savings from Generic Drug Use, at 1 (2012), *available at* http://www.gao.gov/assets/590/588064.pdf.

B. The Food and Drug Administration Amendments Act of 2007

24. The FDA has long sought to manage risks related to pharmaceutical drugs. On September 27, 2007, President George W. Bush signed the Food and Drug Administration Amendments Act of 2007 ("FDAAA") into law, creating section 505-1 of the Federal Food, Drug, and Cosmetic Act ("FDCA").[2] Section 505-1 authorizes the FDA to require a risk evaluation and mitigation strategy ("REMS") for a drug if it determines that a REMS is "necessary to ensure that the benefits of the drug outweigh the risks of the drug." The components of a REMS program can include requirements such as a medication guide and package insert, as well as potential restrictions on distribution of the drug.

25. The statute specifically provides for limited application of REMS to generic drugs. Section 505-1(c) of the FDCA requires that a proposed REMS *for an innovator drug*

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[2] Pub. L. No. 110-85 § 901, 121 Stat. 823, 922, 926 (21 U.S.C. § 355-1).

include numerous elements. In contrast, Section 505-1(i) provides *that a drug that is the subject of an ANDA* is only subject to the more limited REMS restrictions that are required for its RLD.

26. Congress anticipated that brand-name drug companies like Actelion would seek to exploit the REMS provisions by claiming an unrestricted right to refuse to deal with potential generic competitors. Specifically, when Congress established the REMS framework, Congress declared that "No holder of an approved covered application shall use any element to assure safe use required by [FDA] under this subsection to block or delay approval of an [abbreviated new drug application or 505(b)(2) application] or to prevent application of such element . . . to a drug that is the subject of an abbreviated new drug application." 21 U.S.C § 355-1(f)(8).

II. ACTELION'S CAMPAIGN TO ELIMINATE GENERIC DRUG COMPETITION

27. Actelion did not develop the patented technology underlying bosentan. Instead, the only patent listed in the FDA's "Orange Book" with respect to Tracleer is United States Patent No. 5,292,740 ("the '740 Patent"), assigned to Hoffmann-La Roche Inc. of Nutley, New Jersey.

28. Actelion is the exclusive licensee of the '740 Patent.

29. Relying on the technology covered by the '740 Patent, Actelion obtained approval for an NDA to market branded bosentan for the treatment of PAH under the name Tracleer. PAH occurs when blood pressure in the pulmonary artery is too high, causing the right ventricle of the heart to become enlarged. This may result in shortness of breath, fainting, dizzy spells and heart failure.

30. Tracleer is the only FDA approved bosentan pharmaceutical for the treatment of PAH. There are no generic alternatives to Tracleer.

31. Upon information and belief, the price that Actelion charges for Tracleer is extremely high and is well in excess of the cost of production, as is the case for most branded drugs that do not face generic competition.

32. On information and belief, Actelion markets and sells 100% of all FDA-approved pharmaceutical products containing bosentan as the active ingredient in the United States.

33. When Tracleer was approved in 2001, its approval was conditioned on Actelion's implementation of a restricted method of distribution to provide safeguards regarding Tracleer's use. In 2008, pursuant to the FDAAA, the FDA deemed these safety measures that Actelion already had in place qualified as a REMS under the new law.

III. ACTAVIS'S EFFORTS TO OBTAIN TESTING SAMPLES OF BOSENTAN

34. On September 6, 2011, Actavis sent a letter to Actelion requesting samples of Tracleer for analytical and bioequivalence studies. Actavis explained that it was only able to obtain the drug product from Actelion because of the REMS restricted distribution program. Actavis stated that it would comply with the REMS for the RLD, as the FDA's REMS program requires. Actavis offered to pay fair market value for the drug products and to reimburse Actelion for all reasonable costs associated with the request.

35. On September 20, 2011, Actelion denied Actavis's request and stated that the FDCA does not require that Actelion "relinquish its right to choose with whom it does business."

36. Actelion's refusal to supply Tracleer samples is not based on safety concerns. At no time has Actelion specified or offered even to discuss what specific safeguards would address its safety concerns, or the safeguards that Actavis would have to meet in order to obtain testing samples from Actelion. Actelion is well aware that Actavis is an experienced and successful manufacturer of generic drugs, and is perfectly capable of conducting a safe testing program for

generic bosentan. Rather, Actelion baldly asserts an unrestricted right to refuse to supply such samples. Since Actelion is well aware that it is impossible for Actavis, or any generic developer, to submit an ANDA without obtaining samples and performing bioequivalence testing, Actelion's position is not based on safety concerns and any contrary assertion is pretextual. Actelion's conduct is animated solely by its desire to preserve and extend its bosentan monopoly by preventing generic competition.

IV. ACTELION'S EXCLUSIONARY AND MONOPOLISTIC CONDUCT IS CAUSING ANTICOMPETITIVE EFFECTS

37. The relevant product market in this case is the market for FDA-approved bosentan drug products.

38. The relevant geographic market is the United States of America.

39. Actelion, through sales of Tracleer, has a one hundred percent (100%) market share in the relevant market, which is the sale of FDA-approved bosentan tablets to treat PAH in the U.S. Tracleer is the only branded bosentan drug approved to treat PAH, and the FDA approval process for NDAs serves as a significant barrier to new drug entry into this market. There are no generic competitors to Tracleer. The only feasible way for a generic competitor to enter this market requires obtaining a sample of Tracleer, but Actelion has complete control over its distribution. Actelion has a monopoly in the relevant market as well as complete control over the ability of competitors to enter in a way that is economically feasible, and thus exercises monopoly power in the relevant market.

40. Actelion's refusal to sell to generic developers has had anticompetitive effects by preventing, delaying and eliminating competition in the manufacture and sale of bosentan for the treatment of PAH.

41. Actelion's conduct has forced consumers who need bosentan to purchase Tracleer at artificially high and noncompetitive price levels and denied those consumers the availability of a lower cost generic bosentan product. Going forward, consumers who need bosentan will be forced to purchase Tracleer at artificially high and noncompetitive price levels, and will be denied the availability of a lower cost generic bosentan product.

42. Given its history of obtaining final FDA approval for generic pharmaceutical products in a timely fashion, but for Actelion's wrongful conduct, Actavis would have promptly completed studies showing the bioequivalence of that formulation with Tracleer and would have filed an acceptable ANDA with the FDA in late 2011 or early 2012. On information and belief, Actelion's anticompetitive conduct has therefore delayed Actavis's entry into the generic bosentan market.

COUNT I

(Section 2 of the Sherman Act – Monopolization and Attempted Monopolization)

43. Actavis repeats and realleges the allegations in Paragraphs 1 to 42.

44. A nationwide market exists within the United States for the sale of FDA-approved bosentan tablets to treat PAH. Actelion has monopoly power in this market as demonstrated by, *inter alia*, its present monopoly on the sale of bosentan tablets to treat PAH, the high barriers to entry into the market (including those imposed by Actelion), its substantial share of the relevant market(s), and/or and the comparative lack of substitutes.

45. Actelion's monopoly power does not result from the fact that Actelion licenses the '740 Patent, since Actelion will continue to control distribution of Tracleer when the '740 Patent expires or is found invalid. Instead, the distribution restrictions imposed by Actelion as part of its REMS make it the only source from which generic developers can obtain samples for

the purpose of demonstrating bioequivalency. The status of the '740 Patent and Actelion's rights as the licensee of that patent are irrelevant.

46. By refusing to provide samples, Actelion is able to use its monopoly power to prevent the entry of any generic competition because it has made it impossible for generic manufacturers of bosentan to enter the market for FDA-approved bosentan drug products.

47. As a result of Actelion's monopolization and attempted monopolization of the market for FDA-approved bosentan drug products, Actelion has suppressed generic entry and therefore reduced output and increased the prices paid by consumers.

48. A company that possesses monopoly power in the relevant market violates Section 2 of the Sherman Act if it "willfully acquired or maintained that power." *LePage's, Inc. v. 3M*, 324 F.3d 141, 146 (3d Cir. 2003). A monopolist willfully acquires or maintains monopoly power "when it competes on some basis other than the merits." *Id.* at 147.

49. Actelion's exclusionary conduct constitutes unlawful monopolization and attempted monopolization in the relevant market in violation of Section 2 of the Sherman Act. That violation and its anticompetitive effects are continuing and will continue unless injunctive relief is granted.

50. Actelion's suggestion that "samples of Tracleer are unnecessary" because Actavis and other potential generic entrants "can file an NDA [in lieu of an ANDA], just as Actelion's parent company did for Tracleer" is simply not feasible and flatly undermines congressional intent. (Complaint ¶ 44.) The Hatch-Waxman Act specifically provided for this abbreviated process for generic drugs in order to make it economically feasible for generics to enter the market and provide consumers with less expensive products. Withholding samples in order to force generics to go through the NDA process makes it prohibitively expensive and slow for

generics to enter. If Actelion's conduct continues, Actelion will be able to extend its monopoly indefinitely. Congress enacted the Hatch-Waxman Act precisely to avoid this outcome.

51. Actelion's unlawful monopolization and attempted monopolization as set forth above has had the following effects:

a. Competition in the manufacture and sale of bosentan is restrained, suppressed and eliminated;

b. Purchasers of Tracleer are and will be deprived of the benefits of free and open competition in the purchase of Tracleer, and the availability of a lower cost generic bosentan product has been and will be denied, prevented and/or delayed; and

c. Actelion has sold and will continue to sell Tracleer at artificially high and noncompetitive price levels.

52. As a result of Actelion's unlawful conduct alleged herein, Actavis has been injured in its business or property. Specifically, Actelion's unlawful monopolization and attempted monopolization has precluded or substantially delayed the entry of Actavis's generic product in the United States, and as a result Actavis has lost sales and profits as a result and will continue to lose sales and profits as long as Actelion's unlawful conduct is not enjoined by this Court. Such unlawful conduct has also and will in the future increase Actavis's cost of entering into and supplying the market for bosentan.

53. Actavis has suffered damages in an amount to be proven at trial.

COUNT II

(Section 2 of the Sherman Act – Denial of an Essential Facility or Resource Necessary to Compete)

54. Actavis incorporates herein by reference paragraphs 1 through 53.

55. Actelion's conduct also violates Section 2 because it has refused to provide Actavis with access to an essential facility. FDA-approved Tracleer is an essential resource for bioequivalence testing required to obtain FDA approval of a generic bosentan product. As a result, Actelion's distribution of Tracleer is an essential facility for the production of generic bosentan.

56. It is well established that the following four elements are necessary to establish liability under the essential facilities doctrine: (1) control of the essential facility by a monopolist; (2) competitors' inability practically or reasonably to duplicate the essential facility; (3) the denial of the use of the facility to a competitor; (4) the feasibility of providing the facility. *MCI Communications v. AT&T Corp.* 708 F.2d 1081, 1132 (7th Cir. 1983).

57. First, Actelion has complete control over the samples, which are essential to compete with Actelion. Second, Actavis cannot practicably or reasonably duplicate the essential facility. As noted above, the NDA process is not an economically feasible path for generic entry. Third, Actelion has denied Actavis, a competitor, access to Tracleer for the purposes of establishing bioequivalence of a generic product. And finally, it is entirely feasible for Actelion to provide Actavis with the samples; Actavis is willing to pay retail prices and cover any shipping or other related costs.

58. Moreover, there are no legitimate business reasons for Actelion's refusal to deal. The FDA required Actelion to implement REMS restrictions to ensure the safe distribution of

Tracleer. Actavis has developed bioequivalence study protocols that include safeguards to ensure restricted access and patient safety. The REMS restrictions are not a legitimate basis for withholding the samples. Actelion's pretextual refusal to provide the samples prevents generic entry and maintains it monopoly power.

59. Actelion's unlawful monopolization as set forth above has had the following effects:

a. Competition in the manufacture and sale of bosentan is restrained, suppressed and eliminated;

b. Purchasers of Tracleer are and will be deprived of the benefits of free and open competition in the purchase of Tracleer, and the availability of a lower cost generic bosentan product has been and will be denied, prevented and/or delayed; and

c. Actelion has sold and will continue to sell Tracleer at artificially high and noncompetitive price levels.

60. As a result of Actelion's unlawful conduct alleged herein, Actavis has been injured in its business or property. Specifically, Actelion's unlawful monopolization has precluded or substantially delayed Actavis's entry into the generic market in the United States, and Actavis has lost sales and profits as a result and will continue to lose sales and profits as long as Actelion's unlawful conduct is not enjoined by this Court.

61. Actavis has suffered damages in an amount to be proven at trial.

COUNT III

(The New Jersey Antitrust Act, Section 56:9-4 – Monopolization and Attempted Monopolization)

62. Actavis incorporates herein by reference paragraphs 1 through 61.

63. Actelion's anticompetitive conduct constitutes monopolization and attempted monopolization in violation of the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-4.

64. Actelion has improperly extended and maintained its monopoly power in the relevant market as set forth above by unreasonably suppressing generic entry, prolonging Actelion's monopoly, and thereby reducing output and increasing prices paid by consumers.

65. Actelion's unlawful monopoly has had the anticompetitive effects alleged above.

66. As a result of Actelion's unlawful conduct, Actavis has been injured in its business by delaying Actavis's entry into the relevant market.

67. Actavis has suffered damages in an amount to be proven at trial.

COUNT IV

(The New Jersey Antitrust Act, Section 56:9-4 – Denial of an Essential Facility or Resource Necessary to Compete)

68. Actavis incorporates herein by reference paragraphs 1 through 67.

69. Actelion's conduct as set forth above also constitutes monopolization and attempted monopolization in violation of N.J. Stat. Ann. § 56:9-4(a), because it has denied Actavis the use of an essential facility necessary to compete in the relevant market. FDA-approved Tracleer is an essential resource for the bioequivalence testing required to obtain FDA approval of a generic bosentan product. As a result, Actelion's refusal to sell Tracleer to Actavis is an unlawful denial of an essential facility necessary for any competitors to enter the relevant market.

70. Actelion's unlawful monopoly has had the anticompetitive effects alleged above.

71. As a result of Actelion's unlawful conduct, Actavis has been injured in its business by delaying Actavis's entry into the relevant market.

72. Actavis has suffered damages in an amount to be proven at trial.

COUNT V

(Tortious Interference)

73. Actavis incorporates herein by reference paragraphs 1 through 72.

74. Actelion's conduct gives rise to common law liability for tortious interference with prospective business relations and economic advantage.

75. "An action for tortious interference with a prospective business relation protects the right to pursue one's business, calling or occupation free from undue influence or molestation." *Printing Mart v. Sharpe Electronics*, 116 N.J. 739, 750 (1989). The law protects "a [party's] interest in reasonable expectations of economic advantage." *Harris v. Perl*, 197 A.2d 359, 363 (N.J. 1964).

76. The following four facts are necessary to establish liability under the New Jersey tortious interference doctrine: (1) plaintiff must show some protectable right, such as a "prospective economic or contractual relationship;" (2) plaintiff must show that the interference was done intentionally and with "malice," which is "defined to mean that the harm was inflicted intentionally and without justification or excuse;" (3) plaintiff must show that "the interference caused the loss of the prospective gain;" and (4) plaintiff must show "that the injury caused damage." *Printing Mart*, 116 N.J. at 751-752. Each of these facts exists here.

77. First, Actavis has reasonable expectations of economic advantage resulting from its prospective contractual or economic relationships with third parties upon the approval of its generic bosentan product and entry into the relevant market.

78. Second, Actelion intentionally refuses to sell samples of Tracleer to Actavis with the primary purpose of suppressing generic entry and preventing Actavis's resulting prospective economic relationships and advantages. Its conduct is malicious, anticompetitive and an unlawful use of the REMS statute to prevent generic entry. Actelion's intentional infliction of harm is without justification or excuse.

79. Third, if Actelion had not interfered, Actavis would not be delayed in entering the relevant market and would receive the anticipated benefit of sales and profits from generic entry.

80. Fourth, Actelion's interference has directly and proximately caused injury to Actavis's business, as it has delayed Actavis's entry in the relevant market. If Actelion's conduct continues unrestrained, it will not only delay, but entirely prevent Actavis's entry in the relevant market. Actelion has violated New Jersey common law and Actavis is entitled to the damages it suffered as a result of that violation in an amount to be proven at trial.

COUNT VI

(Permanent Injunction)

81. Actavis incorporates herein by reference paragraphs 1 through 80 above as if set forth at length herein.

82. As a result of Actelion's unlawful conduct, as alleged herein, Actavis will suffer immediate and irreparable harm that cannot be fully remedied by money damages.

83. Actavis does not have an adequate remedy at law.

84. Granting injunctive relief to Actavis will not result in greater harm to Actelion.

85. Granting injunctive relief to Actavis will be in the public interest. Among other things, the public will have access to a lower cost, generic bosentan product and there will be competition in the relevant product and geographic markets.

86. Actavis is entitled to a mandatory injunction pursuant to 15 U.S.C. § 26 and Fed. R. Civ. P. 65, as well as N.J. Stat. Ann. § 56:9-10, requiring Actelion to provide Actavis with samples of Actelion's Tracleer for use in bioequivalence testing necessary to obtain approval of an ANDA for a bosentan product.

COUNT VII

(Declaratory Relief)

87. Actavis incorporates herein by reference paragraphs 1 through 87 above as if set forth at length herein.

88. Actavis has requested that Actelion provide Actavis with samples of Actelion's Tracleer for use in bioequivalence testing necessary to obtain approval of an ANDA for a bosentan product. Actavis has agreed to follow procedures that comply with the safety restrictions set forth by the FDA necessary for Actavis to acquire Tracleer from Actelion. Actavis has also agreed to pay Actelion for the samples.

89. As a result of the REMS program that Actelion implemented, described above, Actelion is the only source from which Actavis can acquire Tracleer samples for use in bioequivalence testing.

90. Nevertheless, Actelion has failed and refused to provide samples of Tracleer to Actavis.

91. Accordingly, there is currently a dispute between Actavis and Actelion with respect to Actelion's obligation to provide samples of Tracleer to Actavis for use in bioequivalence testing.

92. Actavis is entitled, pursuant to the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, to a declaration of rights and obligations whereby Actelion is charged with its obligation to provide samples of Tracleer to Actavis for use in bioequivalence testing necessary to obtain approval of an ANDA for a generic bosentan product, and such further relief as is necessary and proper.

PRAYER FOR RELIEF

WHEREFORE Actavis respectfully requests the following relief:

(i) That Actelion's unlawful conduct be declared, adjudicated and decreed a violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, Section 59:9-4 of the New Jersey Antitrust Act, and New Jersey common law on tortious interference;

(ii) That Actavis be granted mandatory injunctive relief enjoining and restraining Actelion from limiting distribution of Tracleer samples to Actavis through use of its REMS and/or "limited distribution" programs or otherwise;

(iii) That Actavis recover compensatory damages for Actavis's lost profits on sales of a generic bosentan product, including treble damages pursuant to 15 U.S.C. § 15 and N.J. Stat. Ann. § 56:9-12;

(iv) That Actavis be awarded expenses and costs of suit, including reasonable attorneys' fees, to the extent provided by law; and

(v) That Actavis be awarded such additional relief as the Court may deem proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Actavis demands a trial by jury on all issues triable by jury.

Dated: December 26, 2012

Respectfully submitted,

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